

REMARKS

Claim Amendments

Claims 9–43 are pending in the Application. Claims 44–71 are newly added. Claims 9–43 are canceled by Applicant without prejudice. Support for the claim amendments is found throughout the specification and in the originally filed claims. No new matter has been added.

Applicant has added independent claim 44, claiming a method of profiling gene expression in a human subject, and has added independent claim 59, claiming a method of characterizing a body state in a human subject. Each of these claims comprises a step of determining, for each gene of a set of genes, a level of RNA encoded by the gene in a blood sample of the subject. The claimed set of genes comprises ZFP and further comprises other genes identified in the specification, including genes identified in Table 2.

Specification support for claiming a method of profiling gene expression in a human subject, and for claiming a method of characterizing a body state in a human subject can be found, for example, at paragraphs [0005], [0006], [0007], [0076] and [0077] of the published application (Pub. No.: US 2005/0196764 A1), which teach that gene expression in blood is reflective of body state, that gene expression profiles in blood can be used to provide information about the state of the human body in health and disease, and that the transcripts detected in whole blood have utility as potential markers of body states, such as diseases.

Specification support for reciting determination of levels of RNA encoded by genes in blood can be found, for example, at the Abstract and paragraphs [0039] and [0076] of the published application, which teach determination of expression levels of genes in blood, such as of genes that are associated with/reflect a health or disease state of a human subject.

Specification support for claiming the set of genes which is recited in each of the instant independent claims can be found, for example, in the Examples section of the published application, which teaches that all of the genes of the set are expressed in blood. The specification teaches that the set includes genes which had not previously been known to be expressed in blood, among which are included genes not expected to be expressed in blood.

Applicant has added dependent claim 45, limiting the human subject of independent

claim 44 to one having a disease, and has added claim 59, similarly limiting the body state recited in independent claim 58 to one which is a disease. Applicant has added claims 46 and 60 limiting the disease to heart failure, and claims 47 and 61 limiting the disease to colorectal cancer. Specification support for limiting the subject to one having a disease such as one of these can be found, for example, in the Examples section of the published application.

Applicant has added dependent claims 48 and 62 limiting the human subject of independent claims 44 and 58 to one which is healthy. Specification support for limiting the subject to one which is healthy can be found, for example, in the Examples section of the published application.

Applicant has added claims 49–56, depending from independent claim 44, and has added claims 63–70, depending from independent claim 58, limiting the step of determining the RNA level of these independent claims to one which is performed using any one of various techniques which find support throughout the specification.

Applicant has added claims 57 and 71, depending from independent claims 44 and 58, respectively, limiting the claimed level of RNA to one which is determined relative to a level of RNA encoded by an internal control gene in the blood sample. Specification support for this limitation can be found, for example, at paragraph [0060] of the published application.

Amendments to the Specification

Applicant has replaced the title of the application with the following title:

“METHOD OF PROFILING GENE EXPRESSION IN A HUMAN SUBJECT”.

Specification support for reciting this title is provided, for example, at paragraph [0007] of the published application.

35 U.S.C. § 102(b)

Claims 13, 14, 23, 37 and 39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Russell et al.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting

prosecution of the instant application, Applicant has now canceled claims 13, 14, 23, 37 and 39, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed claims 44 and 58, and claims depending therefrom.

The rejected claims relate to a method for detecting expression of β MyHC, ANF or ZFP in a blood sample of a human subject. In contrast, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of a set of genes for gene expression profiling of blood which includes specific zinc finger protein genes and genes other than β MyHC, ANF and ZFP genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 102(b).

35 U.S.C. § 102(e)

Claims 13, 15, 18, 23–26, 37–41, and 43 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cocks et al.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting prosecution of the instant application, Applicant has now canceled claims 13, 15, 18, 23–26, 37–41, and 43, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed independent claims 44 and 58, and claims depending therefrom.

The rejected claims relate to a method for detecting expression of β MyHC, ANF or ZFP in a blood sample of a human subject. In contrast, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of a set of genes for gene expression profiling of blood which includes genes other than β MyHC, ANF and ZFP, including specific zinc finger protein genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 102(e).

35 U.S.C. § 103(a) - Cocks et al. in view of Chenchik et al.

Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cocks et al. in

view of Chenchik et al.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting prosecution of the instant application, Applicant has now canceled claim 14, thereby rendering the rejections moot. Concomitantly with canceling this claim, Applicant has now filed independent claims 44 and 58, and claims depending therefrom.

The rejected claim relates to a method for detecting expression of β MyHC, ANF or ZFP in a blood sample of a human subject. In contrast, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of an unpredictable set of genes for gene expression profiling of blood which includes genes other than β MyHC, ANF and ZFP, including specific zinc finger protein genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) - Cocks et al. in view of Sharma et al. and Kruse et al.

Claims 9–11, 37, 38, 41, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cocks et al. in view of Sharma et al. and Kruse et al.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting prosecution of the instant application, Applicant has now canceled claims 9–11, 37, 38, 41 and 42, thereby rendering the rejections moot. Concomitantly with canceling the rejected claims, Applicant has now filed independent claims 44 and 58, and claims depending therefrom.

Claims 9–11 relate to a method of identifying genes differently expressed between subjects having a disease and subjects not having the disease which is performed by detecting differential expression of each gene of a non-specific collection of at least two genes in blood samples from such subjects. Claims 37, 38 and 41 relate to a method for detecting expression of β MyHC, ANF or ZFP in a blood sample of a human subject. Claim 42 relates to a method of screening a human subject for being a candidate for having or being predisposed to a disease which is performed by detecting RNA encoded by a ZFP gene in a blood sample of the subject.

In contrast to the rejected claims, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of a specific and unpredictable set of more

than two genes for gene expression profiling in blood which includes genes other than β MyHC, ANF and ZFP, including specific zinc finger protein genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) - Cocks in view of Sharma et al. and Kruse et al., and Ralph et al.

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cocks in view of Sharma et al. and Kruse et al., and further in view of Ralph et al.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting prosecution of the instant application, Applicant has now canceled claim 12, thereby rendering the rejections moot. Concomitantly with canceling the rejected claim, Applicant has now filed independent claims 44 and 58, and claims depending therefrom.

Claim 12 relates to a method of identifying genes differently expressed between subjects having a disease and subjects not having the disease which is performed by detecting differential expression of each gene of a non-specific collection of at least two genes in blood samples from such subjects. In contrast, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of a specific and unpredictable set of more than two genes for gene expression profiling in blood which includes specific zinc finger protein genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) - Dai et al. in view of Campbell's Biology, Fourth Edition

Claims 13–15, 23, 24, 35, 37 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dai et al. in view of Campbell's Biology, Fourth Edition.

Applicant respectfully traverses the rejections. Nevertheless, in the interest of expediting prosecution of the instant application, Applicant has now canceled claims 13–15, 23, 24, 35, 37 and 38, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed independent claims 44 and 58, and claims depending therefrom.

The rejected claims relate to a method for detecting expression of β MyHC, ANF or ZFP in a blood sample of a human subject. In contrast, the method of the instantly filed claims is performed by determining levels of RNA encoded by each gene of an unpredictable set of genes for gene expression profiling of blood which includes genes other than β MyHC, ANF and ZFP, including specific zinc finger protein genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 103(a).

35 USC § 112, 2nd Paragraph

Claims 27 and 28 are rejected under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the rejections state that claims 27 and 28 refer to “the comparison of step (c).” and that these claims are confusing because there is no antecedent basis for a step (c).

In order to expedite prosecution of the application, Applicant has canceled claims 27 and 28, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed independent claims 44 and 58, and claims depending therefrom, which do not recite a “step (c)”, and which particularly point and distinctly claim the subject matter which Applicant regards as the invention.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the requirements of 35 U.S.C. § 112, 2nd paragraph.

35 USC § 112, 1st Paragraph – Written Description

Claims 41 and 42 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The rejection contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner contends that in claims 41 and 42 the limitation that the blood samples “comprises leukocytes which have not been fractionated into cell types” is new matter.

Applicant respectfully traverses the rejections. Nevertheless, in order to expedite prosecution of the application, Applicant has canceled claims 41 and 42, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed claims 44 and 58, and claims depending therefrom which do not include the limitation that the blood samples “comprises leukocytes which have not been fractionated into cell types”.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the written description requirements of 35 U.S.C. § 112, 1st paragraph.

35 USC § 112, 1st Paragraph, Enablement

Claims 27, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejections contend that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the Examiner contends that the specification does not enable identifying a test subject as a candidate for having or being predisposed to heart failure or cardiac hypertrophy if it is observed that comparison of the individual's level of a zinc finger protein mRNA expression in blood is significantly higher than the level of expression in healthy control subjects. The Examiner further contends that the generic term “zinc finger protein” encompasses a broad family of molecules and that it is highly unpredictable, of all the possible proteins that are “zinc finger proteins” to know which ones would be predictive of or indicative of cardiac hypertrophy or cardiac failure.

Applicant respectfully traverses the rejections. Nevertheless, in order to expedite prosecution of the application, Applicant has canceled claims 27–29, thereby rendering the rejections moot. Concomitantly with canceling these claims, Applicant has now filed claims 44 and 58, and claims depending therefrom.

The rejected claims relate to a method of identifying a test subject as a candidate for

having or being predisposed to a specific disease if the individual's level of expression of a zinc finger protein gene in blood is significantly higher than in healthy subjects. In contrast, the instantly filed claims simply relate to a method of profiling gene expression or characterizing a body state in a human subject which is performed by determining levels of RNA encoded by each gene of a specific and unpredictable set of genes for gene expression profiling in blood, where the set of genes does not recite the generic term "zinc finger protein" but rather includes recitations of specific zinc finger protein genes.

Applicant has demonstrated that the instant claims have an enabled utility for identification of potential markers of disease, such as of heart failure or colorectal cancer, in the declarations dated 3/16/06 and 12/18/06, as graciously indicated by the Examiner in the Office Action dated 03/13/2009 regarding US Patent Application No. 10/268,730 of which the present application is a Division, and in view of the claims of the latter application and of the instant claims being limited to an identical set of genes.

In light of these claim amendments, Applicant respectfully submits that the instant claims satisfy the enablement requirements of 35 U.S.C. § 112, 1st paragraph.

Conclusion

Applicant further submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

A petition for extension of time is attached. However, should any fees be required to ensure consideration of this response, the Commissioner is authorized to charge Deposit Account 04-1105, Reference No. 2053B(204231).

Respectfully submitted,

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